

Applicant: Wilson
Application No.: 10/589,931
Amendment and Response dated November 30, 2009
Reply to Office Action dated May 28, 2009
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REMARKS

STATUS OF CLAIMS

Please amend Claims 1-5, 7, 33-37 and 51; cancel Claims 6, 38, 49 and 50; and add new Claim 73. After entry of this amendment Claim 1-5, 7, 33-37, 51, 55-61, 67-70 and 73 will be pending (with Claims 55-61 and 67-70 withdrawn from consideration). Support for these amendments can be found throughout the specification and originally filed claims. For example, support for the amendment of Claim 1 to include the recitation of “collecting blood from the donor canine animal *after administering a heat-killed E. coli antigen to said donor canine animal*” can be found on page 6, lines 19-20 as well as original Claim 50. Additionally, the subject matter of original Claim 6 has been incorporated into Claim 1, the subject matter of original Claim 38 has been incorporated into Claim 33, and the subject matter of original Claim 50 has been incorporated into Claim 33. No new matter has been added.

OBJECTION TO DISCLOSURE

The specification has been amended to remove the incorporation by reference to Australian Application No. 2004900805. Consequently, the objection to the disclosure under 35 U.S.C. §132(a) is believed to be moot.

OBJECTIONS TO CLAIMS

Claims 1 and 7 have been amended to correct the disparity in indentation previously present.

REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1-7, 33-38 and 49-51 (*sic*) stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Applicant points out that no specific rejection of Claims 49-51 is provided. Nonetheless, as mentioned above, Claims 6, 38, 49 and 50 have been deleted thus rendering any objections to Claims 6, 38, 49 and 50 moot.

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Claims 1 and 33's recitation in step (I) of both phrases "*having a blood group compatible*" and "*having an unmatched blood group*" is allegedly indefinite.

The Examiner should appreciate that compatible donors and recipients can have unmatched blood groups as long as this does not cause a substantial plasma transfusion reaction and/or haemolysis in the recipient canine animal. Applicant points out that US2007/0248612, page 1, paragraph [0013], 2nd column addresses the recitation of the phrase "*canine animal having a blood group compatible with a recipient canine animal having an unmatched blood group*" as it appears in step (I) of Claims 1 and 33.

Claims 2-6 and 34-39 (*sic*) are allegedly indefinite with regard to the phrases "*the canine animal*" and "*said canine animal*".

As noted above, Claims 6 and 38 have been cancelled through this amendment and Claim 39 had previously been cancelled, thereby rendering any objections to Claims 6, 38 and 39 moot. In addition, Claims 2-5 and Claims 34-37 have been amended to include the phrase "*donor*" prior to the phrases "*the canine animal*" and "*said canine animal*". Likewise, Claim 1, 7 and 33 have been amended to include the term "*donor*" prior to the phrase "*canine animal*" as appropriate.

Claim 7 is allegedly indefinite with respect to the relationship of steps (a)-(h) and steps (I)-(III) of Claim 1.

Claim 7 has been amended to replace the phrase "*further including*" with the phrase "*wherein step (II) further includes*" whereby the relationship of the steps recited in Claim 7 with regard to Claim 1 is believed to be clear.

In view of the aforementioned remarks and amendments, Applicant respectfully requests withdrawal of the aforementioned 35 U.S.C. §112, second paragraph rejections.

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REJECTIONS UNDER 35 U.S.C. §103

Claims 1-5 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Natanson *et al.* (Transfusion, 1993) in view of Giger *et al.* (JAMVA, 1995).

Independent Claim 1 has been amended to include the subject matter of former Claim 6 (*i.e.*, wherein the donor canine animal is selected for a phenotype lacking anti-globulin antibodies) which was not deemed obvious. Likewise, Claim 1 has been amended to specify that the blood is collected from the donor canine animal after administering a heat-killed *E. coli* antigen thereto support for which may be found on page 6, lines 19-20 and in original Claim 50 (which was also not deemed obvious). As Claims 2-5 depend on independent Claim 1, and thereby also incorporate its subject matter, Applicant believes the aforementioned 35 U.S.C. §103(a) rejection of Claims 1-5 is now moot.

Claims 1, 7 and 33-37 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Natanson *et al.* (Transfusion, 1993) in view of both Giger *et al.* (JAMVA, 1995) and Harvath *et al.* (Infect & Immun., 1976).

As noted above, independent Claim 1 has been amended to include the subject matter of Claims 6 and 50 which were not deemed obvious. Likewise, Claim 33 has been amended to include the subject matter of Claim 38 (*i.e.*, wherein the donor canine animal is selected for a phenotype lacking anti-globulin antibodies) and Claim 50 (*i.e.*, wherein the *E. coli* is heat-killed) which were not deemed obvious. As Claim 7 (dependent on Claim 1) and Claims 34-37 (dependent on Claim 33) incorporate the subject matter of independent Claims 1 and 33, respectively, Applicant believes the aforementioned 35 U.S.C. §103(a) rejection of Claims 1, 7 and 33-37 is now moot.

Nonetheless, the following arguments are provided regarding the non-obviousness of the presently claimed invention in view of the recited documents (*i.e.*, Natanson *et al.*, Giger *et al.*, and Harvath *et al.*).

Natanson *et al.* examine whether plasma exchange would improve survival in canines with septic shock. Specifically, Natanson *et al.* state, “three of six animals in the plasma exchange group were given their own plasma and the other three animals were given another animal’s plasma” (see natanson et al. page 244, 2nd column, 3rd full paragraph, last sentence). It is noted that Natanson *et al.* teach plasma exchange in canines/dogs where the animals received their own autologous plasma (from a previously frozen stock) *to avoid incompatible reactions*. However, no additional details are provided by Natanson *et al.* with regard to such incompatible reactions. Nevertheless, it is further noted that, “*Natanson et al. would provide motivation for one to provide a compatible plasma, in the event that there might be no previously drawn autologous plasma*” (see Office Action, page 4, 2nd paragraph, last sentence). However, no difference was observed by Natanson *et al.* between the animals treated with their own plasma and those treated with another animal’s plasma. Rather, all animals undergoing plasma exchange according to the method of Natanson *et al.* resulted in decreased survival (i.e., animals die sooner) and worsened cardiovascular performance. Support may, for example, be found on page 243, in the Abstract, page 246, 2nd column and page 247, 2nd column. Natanson *et al.* clearly indicate that the plasma exchange procedure used in their study was harmful and provided no therapeutic benefit (see page 246, 2nd column and page 247, 1st column for support).

In contrast to Natanson *et al.*, the present invention teaches methods of canine plasma isolation and production that significantly improves the quality of canine animal plasma. Furthermore, administration of plasma produced in accordance with the present invention seeks to improve treatment of many medical conditions in the canine, in terms of survival rates, reduction in cost of treatment and shortened periods of hospitalization (see [0178] 1st column on page 9 of US 2007/02486112). Given that the method of plasma exchange taught by Natanson *et al.* ultimately resulted in negative outcomes to the animals receiving the plasma, one of skill in the art would not be motivated to employ the methods for plasma isolation taught by Natanson *et al.*

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Giger *et al.* merely teach that DEA 1.1, DEA 1.2 and DEA 7 are the major antigens that induce reactions of incompatibility when blood products are transfused between dogs.

Giger *et al.* fail to cure the defect of Natanson *et al.* whose methods of plasma exchange are of no therapeutic benefit. The combination of Natanson *et al.* with Giger *et al.* does not lead one of skill in the art to the presently claimed invention. Notably, neither Natanson *et al.* nor Giger *et al.* include the step of administering a heat-killed *E. coli* antigen to the donor canine animal.

Harvath *et al.* teach immunization of dogs with a *Pseudomonas aeruginosa* vaccine.

Harvath *et al.*, however, fail to cure the defect of Natanson *et al.* and Giger *et al.* as noted above.

In short, none of the aforementioned documents, taken alone or in combination disclose or suggest a method of isolating plasma from a canine animal or a method of producing hyperimmunised canine animal plasma as recited in the presently claimed invention. Applicant submits that Claims 1-5, 7, 33-37, 51 and 73 are not obvious in view of the aforementioned documents taken alone, or in combination.

Claim 49 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Natanson *et al.* (Transfusion, 1993) in view of both Giger *et al.* (JAMVA, 1995) and Harvath *et al.* (Infect & Immun., 1976) and further in view of Emery *et al.* (U.S. Patent No. 3,950,512). As noted above, Claim 49 has been deleted, thereby rendering this objection moot.

In view of the aforementioned amendments and remarks, Applicant respectfully requests withdrawal of these 35 U.S.C. §103 rejections of Claims 1-5, 7, 33-37 and 49.

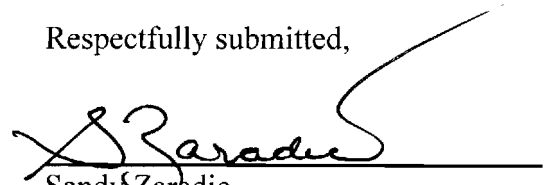
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CONCLUSION

Applicant believes Claims 1-5, 7, 33-37, 51 and 73 are in condition for allowance and respectfully request the same. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicant's attorney at the number listed below.

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